



3-19-05

SPR 1615

PATENT  
ATTORNEY DOCKET NO. 001942.00007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Confirmation No.: 9843
Eija Pirhonen et al.	)	
Serial No.: 10/006,796	)	Examiner: Micah Paul Young
Filed: December 4, 2001	)	Art Unit: 1615
Title: Biodegradable Implant and Method for Manufacturing One	)	

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

In regard to the above-identified application, we are transmitting herewith the attached:

1. Supplemental Information Disclosure Statement;
2. USPTO Form 1449 with fifty-one (51) References;
3. FY2005 Fee Transmittal (in duplicate); and
4. Return Receipt Postcard.

and hereby certify that this correspondence is being deposited on the date indicated below with the United States Postal Service as Express mail EV 515 645 160 US in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

With respect to additional fees, the Commissioner is hereby authorized to charge any fees or credit overpayment, to our Deposit Account No. 19-0733. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Dated:

*March 9, 2005*

*Gregory J. Cohan*  
Gregory J. Cohan, Reg. No. 40,959  
BANNER & WITCOFF, LTD.  
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Effective on 12/08/2004.  
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).**FEE TRANSMITTAL  
for FY 2005**☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$) 180.00**Complete If Known**

Application Number	10/006,796
Filing Date	December 4, 2001
First Named Inventor	Eija Pirohonen et al.
Examiner Name	Micah Paul Young
Art Unit	1615
Attorney Docket No.	001942.00007

**METHOD OF PAYMENT** (check all that apply)☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify) : \_\_\_\_\_☒ Deposit Account Deposit Account Number: 19-0733 Deposit Account Name: **Banner & Witcoff, LTD.**

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or underpayments of fee(s) ☒ Credit any overpayments

Under 37 CFR 1.16 and 1.17

**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee(\$)	Fee(\$)	Small Entity Fee(\$)	Fee(\$)	Small Entity Fee(\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES****Fee Description**

Each claim over 20 (including Reissues)

Each independent claim over 30 (including Reissues)

Multiple dependent claims

Total Claims	Extra Claims	Fee(\$)	Fee Paid (\$)
___ -20 or HP= 0	x	50.00	= 0.00

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee(\$)	Fee Paid (\$)
___ - 3 or HP= 0	x		= 0

HP = highest number of independent claims paid for, if greater than 3.

Small Entity	
Fee (\$)	Fee (\$)
50	25
200	100
360	180
Multiple Dependent Claims	
Fee (\$)	Fee Paid (\$)
0.00	0.00

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
___ - 100 = ___	/ 50 = ___	(round up to a whole number) x		= 0

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge) : **Fee Under Rule 1.17(P)****180.00****SUBMITTED BY**

Signature		Registration No. (Attorney/Agent)	40,959	Telephone	(617) 720-9600
Name (Print/Type)	Gregory J. Cohan	Date	March 9, 2005		

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



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Serial No.: 10/006,796	)	Examiner: Micah Paul Young
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with the provisions of 37 C.F.R. §§1.56 and 1.97, Applicant herewith submits the publications and/or patents shown on the attached form PTO-1449, for consideration by the Examiner in connection with the examination of the above-identified patent application.

03/14/2005 JBALINAN 00000101 190733 10006796  
01 FC:1806 180.00 DA

REMARKS

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed (CHECK ONE):

- (1) within three (3) months of the **Filing Date** or before the mailing date of the **First Office Action** on the merits; or
- X (2) after the period defined in (1) but before the mailing date of a **Final Rejection** or **Notice of Allowance**, and the requisite Certification or fee

U.S.S.N. 10/006,796  
Express Mail Receipt No.: EV 515 645 160 US

under Rule 1.17(p), namely **\$180.00**, is included herein; or

- (3) after the mailing date of a **Final Rejection** or **Notice of Allowance** but before the payment of the **Issue Fee**, and the requisite Certification and fee are included herein.

It is respectfully requested that each of the documents shown on the attached form(s) PTO-1449 be made of record in this application. Copies of these documents (CHECK ONE):

X are enclosed herewith; or

— are in the file of related application Serial No. 00/000,000, filed \_\_\_\_\_, and are thus not being resubmitted herein.

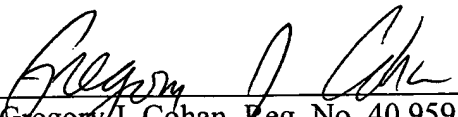
Early examination and allowance of the present application are respectfully solicited.

### FEE AUTHORIZATION

The Commissioner is hereby authorized to charge any fee associated with this document to **Deposit Account No. 19-0733**. Any overpayments should be credited to same Deposit Account.

Respectfully submitted,

Dated: March 9, 2005

  
Gregory J. Cohan, Reg. No. 40,959  
BANNER & WITCOFF, LTD.  
28 State Street, 28th Floor  
Boston, MA 02109  
(617) 720-9600

Attorney Docket No.  
001942.00007Serial No.  
10/006,796

## INFORMATION DISCLOSURE CITATION

Sheet 1 of 3

Applicants: Eija Pirhonen et al.

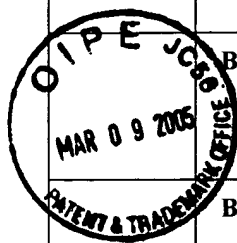
Filing Date: December 4, 2001

Group: 1615

## U.S. PATENT DOCUMENTS

Examiner Initial	Patent No.	Date	Name	Class	Subclass	Filing Date (if appropriate)
	AA 4,142,293	03/06/1979	Tieche	32	15	02/28/1977
	AB 4,603,695	08/05/1986	Ikada et al.	128	334 R	06/29/1984
	AC 4,776,329	10/11/1988	Treharne	128	92 YR	09/20/1985
	AD 4,863,472	09/05/1989	Tormala et al.	623	16	
	AE 4,905,679	03/06/1990	Morgan	606	70	02/22/1988
	AF 4,961,707	10/09/1990	Magnusson et al.	433	215	06/06/1989
	AG 4,973,333	11/27/1990	Treharne	606	77	08/10/1988
	AH 5,093,179	03/03/1992	Scantlebury et al.	428	158	05/07/1991
	AI 5,108,399	04/28/1992	Eitenmuller et al.	606	77	09/15/1989
	AJ 5,275,601	01/04/1994	Gogolewski et al.	606	72	09/03/1991
	AK 5,466,262	11/14/1995	Saffran	623	16	08/30/1993
	AL 5,480,436	01/02/1996	Bakker et al.	623	11	07/15/1994
	AM 5,486,593	01/23/1996	Tang et al.	528	370	09/23/1994
	AN 5,503,164	04/02/1996	Friedman	128	898	01/28/1994
	AO 5,525,646	06/11/1996	Lundgren et al.	523	105	
	AP 5,569,250	10/29/1996	Sarver et al.	606	69	03/01/1994
	AQ 5,601,429	02/11/1997	Blacklock	433	174	08/11/1995
	AR 5,601,553	02/11/1997	Trebing et al.	606	61	10/03/1994
	AS 5,660,225	08/26/1997	Saffran	623	16	11/13/1995
	AT 5,700,479	12/23/1997	Lundgren	424	435	11/10/1994
	AU 5,791,352	08/11/1998	Reich et al.	128	898	11/08/1996
	AV 5,868,749	02/09/1999	Reed	606	76	01/31/1997
	AW 6,169,046	01/02/2001	Shikata et al.	442	361	03/19/1998
	AX 6,269,716	08/07/2001	Amis	81	121.1	
	AY 6,343,531	02/05/2002	Amis	81	121.1	06/25/2001
	AZ 6,477,923	11/12/2002	Amis	81	121.1	09/25/2001

	BA	6,531,146	03/11/2003	Calhoun et al.	424	426	03/12/2001
OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)							
	BB	Smart Screw Brochure from BIONX IMPLANTS Inc., Undated					
	BC	R. Suuronen, P. Lane, E. Sarkiala, T. Pohjonen, and C. Lindqvist: <i>Sagittal split osteotomy fixed with biodegradable, self-reinforced poly-L-lactide screws. A pilot study in sheep.</i> Int. J. Oral Maxillofac. Surg. 1992;21:303-308					
	BD	E. Partio, O. Bostman, E. Hirvensalo, S. Vainionpaa, K. Vihtonen, H. Patiala, P. Tormala, and P. Rokkanen: <i>Self-Reinforced Absorbable Screws in the Fixation of Displaced Ankle Fractures: A Prospective Clinical Study of 152 Patients.</i> Journal of Orthopaedic Trauma, Vol. 6, No. 2, pp. 209-215					
	BE	<a href="http://www.macropore.com/usa_products/os_reconstruct.htm">http://www.macropore.com/usa_products/os_reconstruct.htm</a> ; Page from Macropore website entitled "MacroPore OS™ Reconstruction System_					
	BF	Abstract from article entitled <i>Biodegradation and biocompatibility of a guided tissue regeneration barrier membrane formed from a liquid polymer material.</i> J Biomed Mater Res. 1998 Nov.; 42(2):303-11					
	BG	Abstract from article entitled <i>Comparison of a bioabsorbable GTR barrier to a non-absorbable barrier in treating human class II furcation defects. A multi-center parallel design randomized single-blind trial.</i> J Periodontol. 1997 Jul; 68(7): 667-75					
	BH	Abstract from article entitled <i>Periodontal regeneration in naturally occurring Class II furcation defects in beagle dogs after guided tissue regeneration with bioabsorbable barriers.</i> J Periodontol. 1997 Jun; 68(6): 563-44					
	BI	Abstract from article entitled <i>Guided tissue regeneration in human furcation defects after using a biodegradable barrier: a multi-center feasibility study.</i> J Periodontol. 1995 May; 66(5): 377-85.					
	BJ	P.Sullivan, D. Rosenstein, R. Holmes, D.Craig and P. Manson: <i>Bone-Graft Reconstruction of the Monkey Orbital Floor with Iliac Grafts and Titanium Mesh Plates: A Histometric Study.</i> Plastic and Reconstructive Surgery, 91:769, 1993.					
	BK	Rudolf Robert Maria Bos: <i>Ploy(L-lactide) Osteosynthesis development of bioresorbable bone plates and screws.</i> University of Groningen, The Netherlands 1989					
	BL	F.Rozema, R.R.M. Bos, A. Pennings, and H.W.B. Jansen: <i>Poly(L-Lactide) Implants in Repair of Defects of the Orbital Floor: An Animal Study.</i> Journal of Oral Maxillofac Surg., 48:1305-1309, 1990.					
	BM	L. Pineda, M. Busing, R. Meinig and S. Gogolewski: <i>Bone regeneration with resorbable polymeric membranes. III. Effect of poly(L-lactide) membrane pore size on the bone healing process in large defects.</i> Journal of Biomedical Materials Research, Vol. 31, 385-394 (1996).					
	BN	510(k) Summary: Bionc Implants Inc.'s ThermoFX Mesh Bioabsorbable Fixation Plate; November 15, 2000					
	BO	510(k) Summary: MacroPoreOS Protective Sheet; April 27, 2001					
	BP	510(k) Summary: Resorb-X Resorbable Plating System; March 20, 2002					
	BQ	510(k) Summary: OsteoMed Bioresorbable Fixation System; July 31, 2001					
	BR	510(k) Summary of Safety and Effectiveness: RESOLUT Regenerative Material; July 3, 1996					
	BS	510(k) Summary of Safety and Effectiveness: RESOLUT Regenerative Material; March 6, 1997					
	BT	K994158 Summary: MacroPoreOS Protective Sheet; July 24, 2000					
	BU	510(k) Summary: MacroPore OS Trauma System; July 1, 2002					



BV	K994158 Summary: MacroPoreOS Protective Sheet; July 24, 2000
BW	H. Peltoniemi, R. Tulamo, H. Pihlajamaki, M. Kallioinen, T. Pohjonen, P. Tormala, P. Rokkanen, and T. Waris: <i>Consolidation of Craniotomy Lines after Resorbable Polylactide and Titanium Plating: A Comparative Experimental Study in Sheep</i> . Plastic and Reconstructive Surgery, January 1998
BX	H. Peltoniemi, R. Tulamo, H. Pihlajamaki, M. Kallioinen, T. Pohjonen, P. Tormala, P. Rokkanen, and T. Waris: <i>The Healing of Cranial Osteomy Lines Fixed with SR-PLLA Plates and Titanium Screws: an Experimental Study in Growing Sheep</i> . Transactions of the 11 <sup>th</sup> Congress of the International Confederation of Plastic, Reconstructive and Aesthetic Surgery, p. 630, Yokohama, Japan, April 16-21, 1995.
BY	B. Eppley and A.M. Sadove: <i>A Comparison of Resorbable and Metallic Fixation in Healing of Calvarial Bone Grafts</i> . Plastic and Reconstructive Surgery, Vol. 96, No.2 August 1995.

EXAMINER	DATE CONSIDERED
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant. \*\*Copies of references not provided at the time of this submission.